

## REQUEST FOR ACCESS TO AN APPLICATION UNDER 37 CFR 1.14(e)

In re Application of

Application Number

08/246,034

Filed

5/18/94

Art Unit

Examiner

Paper No. \_\_\_\_\_

Assistant Commissioner for Patents  
Washington, DC 20231

1.  I hereby request access under 37 CFR 1.14(e)(2) to the application file record of the above-identified ABANDONED Application, which is not within the file jacket of a pending Continued Prosecution Application (CPA) (37 CFR 1.53(d)) and is: (CHECK ONE)

(A) referred to in:

United States Patent Application Publication No. \_\_\_\_\_, page \_\_\_\_\_, line \_\_\_\_\_.

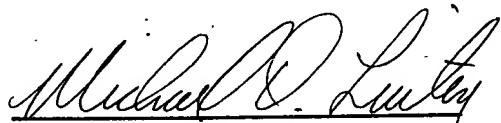
United States Patent Number 6509006, column Face, line \_\_\_\_\_, or

an International Application which was filed on or after November 29, 2000 and which

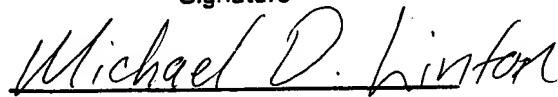
designates the United States, WIPO Pub. No. \_\_\_\_\_, page \_\_\_\_\_, line \_\_\_\_\_.

(B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11(b) or 1.14(e)(2)(i), i.e., Application No. \_\_\_\_\_, paper No. \_\_\_\_\_, page \_\_\_\_\_, line \_\_\_\_\_.

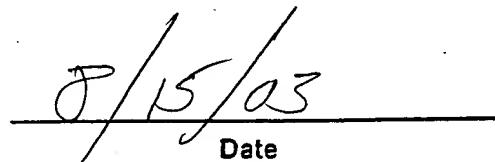
2.  I hereby request access under 37 CFR 1.14(e)(1) to an application in which the applicant has filed an authorization to lay open the complete application to the public.



Signature



Typed or printed name



Date

FOR PTO USE ONLY

Approved by: \_\_\_\_\_  
(initials)

Unit: \_\_\_\_\_



US006509006B1

(12) **United States Patent**  
Platz et al.

(10) **Patent No.:** US 6,509,006 B1  
(45) **Date of Patent:** Jan. 21, 2003

(54) **DEVICES COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF AEROSOLIZED MEDICAMENTS**

(75) Inventors: Robert M. Platz, Half Moon Bay, CA (US); John S. Patton, San Carlos, CA (US); Linda Foster, Sunnyvale, CA (US); Mohammed Eljamal, San Jose, CA (US)

(73) Assignee: Inhale Therapeutic Systems, Inc., San Carlos, CA (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/427,075

(22) Filed: Oct. 26, 1999

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 08/417,507, filed on Apr. 4, 1995, now abandoned, and a continuation of application No. 08/383,475, filed on Feb. 1, 1995, and a continuation of application No. 08/313,707, filed on Sep. 27, 1994, and a continuation of application No. 08/309,691, filed on Sep. 21, 1994, and a continuation of application No. 08/246,034, filed on May 18, 1994, and a continuation of application No. 08/232,849, filed on Apr. 25, 1994, and a continuation of application No. 08/044,358, filed on Apr. 7, 1993, and a continuation-in-part of application No. 07/910,048, filed on Jul. 8, 1992.

(51) Int. Cl. 7 ..... A61K 9/12; A61K 9/14

(52) U.S. Cl. ..... 424/46; 424/45; 424/489

(58) Field of Search ..... 424/45, 46, 489

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

2,598,525 A	5/1952	Fox
3,202,731 A	8/1965	Grevenstuk et al.
3,300,474 A	1/1967	Fodlin et al.
3,314,803 A	4/1967	Tarrytown et al.
3,362,405 A	1/1968	Hazel
3,425,600 A	2/1969	Abplanalp
3,540,927 A	11/1970	Nuumi et al.
3,554,768 A	1/1971	Feldman
3,608,066 A	9/1971	Illartein
3,620,776 A	11/1971	Mishkin et al.
3,666,496 A	5/1972	Honey et al.
3,674,901 A	7/1972	Shepherd et al.
3,764,716 A	10/1973	Rainwater et al.
3,921,637 A	11/1975	Bennie et al.
3,964,483 A	6/1976	Mathes
3,971,852 A	7/1976	Brenner et al.
3,991,304 A	11/1976	Hillsman
3,991,761 A	11/1976	Cocozza
3,994,421 A	11/1976	Hansen
4,036,223 A	7/1977	Obert
4,069,819 A	1/1978	Valentini et al.
4,098,273 A	7/1978	Glcnn
4,109,019 A	8/1978	Moore
4,153,689 A	5/1979	Hiral et al.
4,206,200 A	6/1980	Guthöhrlein et al.
4,249,526 A	2/1981	Dean et al.
4,253,468 A	3/1981	Lehmbeck

4,294,624 A	10/1981	Veltman
4,294,829 A	10/1981	Suzuki et al.
4,338,931 A	7/1982	Cavazza
4,423,079 A	12/1983	Kline
4,446,862 A	5/1984	Baum et al.
4,452,239 A	6/1984	Malem
4,484,577 A	11/1984	Sackner et al.
4,503,035 A	3/1985	Pestka et al.
4,533,552 A	8/1985	Kawamata et al.
4,534,343 A	8/1985	Nowacki et al.

(List continued on next page.)

**FOREIGN PATENT DOCUMENTS**

BE	902 257	8/1985
DE	18 12 574	6/1970
DE	24 15 159	10/1975
DE	31 41 498	4/1983
DE	01 61 072	9/1984
EP	0 015 123	9/1980

(List continued on next page.)

**OTHER PUBLICATIONS**

US 5,849,884, 12/1998, Wolszwillo et al. (withdrawn)

J. Hanes et al. (1997). Proc. Int'l Symp. Control Rel. Bioactive Matter 24:57-58.\*

Andrew, Edmund L., "Gelatin Capsules Revamped For New Generation Of Pills," *New York Times*, Saturday, Sep. 16, 1992, 19 (N), 35 (L), col 5, 9 col in.

Annear, D. I., "Observations on Drying Bacteria From the Forzen and From the Liquid State," *Austral. J. Exp. Biol.* vol. 36, pp. 211-221.

(List continued on next page.)

*Primary Examiner*—Jose' G. Dees

*Assistant Examiner*—Mina Haghighatian

(74) *Attorney, Agent, or Firm*—Burns Doane Swecker & Mathis LLP

(57) **ABSTRACT**

According to the subject invention, dispersible dry powder pharmaceutical-based compositions are provided, including methods for their manufacture and dry powder dispersion devices. A dispersible dry powder pharmaceutical-based composition is one having a moisture content of less than about 10% by weight (% w) water, usually below about 5% w and preferably less than about 3% w; a particle size of about 1.0-5.0  $\mu\text{m}$  mass median diameter (MMD), usually 1.0-4.0  $\mu\text{m}$  MMD, and preferably 1.0-3.0  $\mu\text{m}$  MMD; a delivered dose of about >30%, usually >40%, preferably >50%, and most preferred >60%; and an aerosol particle size distribution of about 1.0-5.0  $\mu\text{m}$  mass median aerodynamic diameter (MMAD), usually 1.5-4.5  $\mu\text{m}$  MMAD, and preferably 1.5-4.0 MMAD. Such composition are of pharmaceutical grade purity.

2 Claims, No Drawings